

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC. and ABBVIE)
DEUTSCHLAND GMBH & CO. KG,)
)
Plaintiffs,)
) C.A. No. _____
v.)
)
CIPLA LIMITED)
and CIPLA USA, INC.,)
)
Defendants.)

COMPLAINT

Plaintiffs AbbVie Inc. (“AbbVie Inc.”) and AbbVie Deutschland GmbH & Co. KG (“AbbVie Deutschland”) (collectively “AbbVie”) by way of complaint against Cipla Limited (“Cipla Ltd.”) and Cipla USA Inc. (“Cipla USA”)(collectively, “Cipla” or “Defendants”) states as follows:

THE PARTIES

1. AbbVie Inc. is a company organized and existing under the laws of Delaware with its principal place of business at 1 North Waukegan Road, North Chicago, Illinois 60064. AbbVie is a global biopharmaceutical research based biopharmaceutical company engaged in the business of research, development, manufacture, and sale of pharmaceutical products throughout the world.

2. AbbVie Deutschland GmbH & Co. KG is a limited partnership organized and existing under the laws of Germany with its registered address at Mainzer Straße 81, 65189 Wiesbaden, Germany. AbbVie Deutschland GmbH & Co. KG is governed by its General Partner, AbbVie Komplementär GmbH, and is a wholly-owned foreign subsidiary of AbbVie Inc.

3. On information and belief, Cipla Ltd. is a corporation organized and existing under the laws of India having a registered office at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai, 400 013, India.

4. On information and belief, Cipla USA is a Delaware corporation having a principal place of business at 9100 S Dadeland Blvd. Suite 1500, Miami, Florida 33156.

5. On information and belief, Cipla USA is registered to transact business in Delaware and has appointed a registered agent for service of process (Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808).

6. On information and belief, Cipla USA is a subsidiary of Cipla Ltd.

NATURE OF THE ACTION

7. This is a civil action for patent infringement of: (1) United States Patent Number 7,148,359 B2 as amended by the Inter Partes Reexamination Certificate (1272nd), issued May 23, 2016, also known as United States Patent No. 7,148,359 C1 (together “the ’359 Patent”); (2) United States Patent Number 7,364,752 B1 as amended by the Inter Partes Reexamination Certificate (1039th) issued January 23, 2015, also known as United States Patent No. 7,364,752 C1 (together “the ’752 Patent”); (3) United States Patent Number 8,025,899 B2 (“the ’899 Patent”); (4) United States Patent Number 8,268,349 B2 (“the ’349 Patent”); (5) United States Patent Number 8,309,613 B2 (“the ’613 Patent”); (6) United States Patent Number 8,377,952 B2 (“the ’952 Patent”); (7) United States Patent Number 8,399,015 B2 (“the ’015 Patent”); (8) United States Patent Number 8,470,347 B2 (“the ’347 Patent”); and (9) United States Patent Number 8,691,878 B2 (“the ’878 Patent”) (collectively “the Patents-in-Suit”). This civil action arises under the United States Patent Laws, Title 35, United States Code, §§ 1 et seq., in particular under 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This civil action relates to Abbreviated New Drug Application (“ANDA”) No. 090-371,

which Cipla filed or caused to be filed under 21 U.S.C. § 355(j) with the United States Food and Drug Administration (“FDA”) for approval to market generic copies of AbbVie’s successful Kaletra® tablet products that are sold in the United States.

JURISDICTION AND VENUE

8. This is a civil action for patent infringement and declaratory judgment arising under the patent laws of the United States, 35 U.S.C. § 100 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

9. On information and belief, this Court has personal jurisdiction over Cipla because of, among other things, its marketing and sales activities in this judicial district, including but not limited to the substantial, continuous, and systematic distribution, marketing, and/or sales of pharmaceutical products in this judicial district; its plan to distribute and sell its infringing ANDA products in this judicial district coupled with its affirmative act of filing its ANDA for the purpose of engaging in that injury-causing and allegedly wrongful marketing conduct in this judicial district; and the fact that it has availed itself of the rights afforded in this judicial district.

10. On information and belief, Cipla develops, formulates, manufactures, imports, markets, and sells various generic pharmaceutical drug products, and regularly conducts business, throughout the United States, including in the State of Delaware, through various directly or indirectly-owned subsidiaries, including for example Cipla USA.

11. On information and belief, Cipla USA imports, markets, and sells various generic pharmaceutical drug products, and regularly conducts business, through the United States, including in the State of Delaware, for example on behalf of and at the direction of Cipla Ltd.

12. On information and belief, Cipla has purposefully conducted and continues to conduct substantial business in this judicial district, from which it has derived, directly or

indirectly, substantial revenue.

13. Upon information and belief, Cipla Ltd. has filed an ANDA, and/or been actively involved in the preparation and submission of an ANDA, for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the generic drug product described in ANDA No. 090-371 in the United States, including Delaware.

14. Upon information and belief, Cipla USA has been actively involved in the preparation and submission of an ANDA, on behalf of Cipla Ltd. for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the generic drug product described in ANDA No. 090-371 in the United States, including Delaware.

15. On information and belief, Cipla will act in concert, and intends to offer to sell and sell in this judicial district, the generic drug product that will be manufactured as a result of any FDA approval of Cipla's ANDA No. 090-371, and based upon information and belief, this judicial district will be a destination of products that will be manufactured and sold as a result of any FDA approval of Cipla's ANDA No. 090-371.

16. On information and belief, this Court has personal jurisdiction over Cipla USA because Cipla USA is qualified and registered to do business in the State of Delaware, has appointed a registered agent in Delaware, and holds current and valid "Pharmacy-Wholesale" and "Distributor/Manufacturer CSR" Licenses in Delaware.

17. On information and belief, Cipla Ltd. and/or Cipla USA have previously submitted to the jurisdiction of this Court and asserted counterclaims arising under the Patent Laws of the United States in other civil actions initiated in this Court. *See, e.g.,* Answer at 3, 14–22, *Biogen International GmbH et al. v. Cipla Ltd. et al.*, No. 17-cv-00851 (D. Del. Oct. 16,

2017) (D.I. 10); Answer at 2, 15–20, *Onyx Therapeutics, Inc. v. Cipla Ltd. et al.*, No. 16-cv-00988 (D. Del. Jan. 13, 2017) (D.I. 12).

18. Cipla is subject to specific personal jurisdiction in this District based on the filing of its ANDA with Paragraph IV certifications regarding the Patents-in-Suit with the intention of distributing and selling the products that are the subject of Cipla's ANDA No. 090-371 in Delaware. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755 (Fed. Cir. 2016).

19. As in *Acorda Therapeutics*, Cipla “has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at,” on information and belief, this District and elsewhere. *Acorda Therapeutics*, 817 F.3d at 759.

20. Cipla’s “ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs.” *Acorda Therapeutics*, 817 F.3d at 760.

21. As in *Acorda Therapeutics*, on information and belief, Cipla “intends to direct sales of its drugs into [Delaware], among other places, once it has the requested FDA approval to market them.” *Acorda Therapeutics*, 817 F.3d at 758.

22. On information and belief, Cipla will cause its proposed Generic Lopinavir/Ritonavir Tablets that are the subject of Cipla's ANDA No. 090-371 to be sold in Delaware, upon approval of its ANDA.

23. Cipla's ANDA filing, including its Paragraph IV certifications regarding the Patents-in-Suit, is suit-related and has a substantial connection with this District because it reliably, non-speculatively predicts activities in this District by Cipla.

24. “[T]he minimum-contacts standard is satisfied by the particular actions [Cipla] has already taken—its ANDA filing[]—for the purpose of engaging in that injury-causing and

allegedly wrongful marketing conduct in” this District. *Acorda Therapeutics*, 817 F.3d at 760.

25. This Court also has personal jurisdiction over Cipla by virtue of the fact that, among other things, Cipla has committed, or aided, abetted, contributed to, and/or participated in the commission of the tortious act of patent infringement that has led to foreseeable harm and injury to AbbVie, a Delaware corporation.

26. Exercising personal jurisdiction over Cipla in this District would not be unreasonable given Cipla’s contacts in this District, the fact that AbbVie is a Delaware corporation, and the interest in this District of resolving disputes related to products to be sold herein.

27. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

28. Venue is proper in this judicial district because Cipla USA is incorporated in Delaware and Cipla Ltd. is incorporated in India, has its principal place of business in India, and has as its only U.S. subsidiary Cipla USA.

BACKGROUND

29. AbbVie is the holder of approved New Drug Application (“NDA”) No. 21-906 for lopinavir/ritonavir tablets, 100 mg/25 mg and 200 mg/50 mg, which AbbVie markets and sells under the trademark Kaletra®. AbbVie manufactures and sells Kaletra® tablets in the United States under NDA No. 21-906.

30. Cipla filed with the FDA ANDA No. 090-371 under 21 U.S.C. § 355(j)(1) and (2)(A), seeking FDA approval to market lopinavir/ritonavir tablets, 100 mg/25 mg and 200 mg/50 mg (“Cipla’s Generic Lopinavir/Ritonavir Tablets”), which are generic copies of AbbVie’s Kaletra® tablets.

31. Upon information and belief, Cipla’s ANDA No. 090-371 seeks FDA approval of pharmaceutical compositions comprising lopinavir/ritonavir in 100 mg/25 mg and 200 mg/50 mg

dosage strengths.

32. Upon information and belief, Cipla's ANDA No. 090-371 seeks FDA approval to market Cipla's Generic Lopinavir/Ritonavir Tablets in the United States. On September 27, 2017, AbbVie received a letter on behalf of Cipla, dated September 26, 2017, purporting to be a "Notification of Paragraph IV Certification Regarding NDA 21906 (Lopinavir / Ritonavir Tablets 200mg/ 50mg; & 100mg/ 25mg With Respect to U.S. Patent Nos. 7,148,359; 6,364,752; 8,025,899; 8,268,349; 8,309,613; 8,377,952; 8,399,015; 8,470,347; and 8,691,878" ("Notice Letter"). Cipla's Notice Letter notified AbbVie that Cipla had filed ANDA No. 090-371, seeking approval to market Cipla's Generic Lopinavir/Ritonavir Tablets. The Notice Letter also states that "Cipla has certified in the Cipla ANDA that, in its opinion and to the best of its knowledge, the '359, '752, '899, '348, '613, '952, '015, '347, and '878 patents are invalid and/or will not be infringed by Cipla's ANDA Product."

33. Cipla's Notice Letter purported to include an "Offer of Confidential Access" to Cipla's ANDA. However, the proposed terms of Cipla's Offer of Confidential Access ("OCA") were unreasonable. On October 6, 2017, counsel for AbbVie sent proposed revisions to the OCA to counsel for Cipla. Cipla's outside counsel failed to timely respond to AbbVie's correspondence regarding the terms, waiting until November 7, 2017 to propose further revisions to the OCA. Cipla's delay did not allow for sufficient time to finalize the OCA and then analyze the Cipla's ANDA prior to filing suit. Consequently, AbbVie was not provided a copy of ANDA No. 090-371 prior to suit.

THE PATENTS-IN-SUIT

34. The '359 Patent was originally duly and legally issued by the U.S. Patent and Trademark Office ("PTO") on December 12, 2006. The '359 Patent was the subject of a reexamination proceeding before the PTO. On May 23, 2016, after the conclusion of the

reexamination proceeding, the PTO issued an Inter Partes Reexamination Certificate (1272nd), which amended the '359 Patent as United States Patent No. 7,148,359 C1. AbbVie is the owner by assignment of the '359 Patent and has the right to sue for infringement thereof. AbbVie lists the '359 Patent in the Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") for NDA No. 21-906. A true and correct copy of the '359 Patent is attached as Exhibit A.

35. The '752 Patent was originally duly and legally issued by the PTO on April 29, 2008, as United States Patent No. 7,364,752 B1. The '752 Patent was the subject of reexamination proceedings before the PTO. On January 23, 2015, after the conclusion of the reexamination proceedings, the PTO issued an Inter Partes Reexamination Certificate (1039th), which amended the '752 Patent as United States Patent No. 7,364,752 C1. AbbVie Inc. is the owner by assignment of the '752 Patent and has the right to sue for infringement thereof. AbbVie lists the '752 Patent in the Orange Book for NDA 21-906. A true and correct copy of the '752 Patent is attached as Exhibit B.

36. The '899 Patent was duly and legally issued by the PTO on September 27, 2011. AbbVie Inc. is the owner by assignment of the '899 Patent and has the right to sue for infringement thereof. AbbVie lists the '899 Patent in the Orange Book for NDA No. 21-906. A true and correct copy of the '899 Patent is attached as Exhibit C.

37. The '349 Patent was duly and legally issued by the PTO on September 18, 2012. AbbVie Inc. is the owner by assignment of the '349 Patent and has the right to sue for infringement thereof. AbbVie lists the '349 Patent in the Orange Book for NDA No. 21-906. A true and correct copy of the '349 Patent is attached as Exhibit D.

38. The '613 Patent was duly and legally issued by the PTO on November 13, 2012.

AbbVie Inc. is the owner by assignment of the '613 Patent and has the right to sue for infringement thereof. AbbVie lists the '613 Patent in the Orange Book for NDA No. 21-906. A true and correct copy of the '613 Patent is attached as Exhibit E.

39. The '952 Patent was duly and legally issued by the PTO on February 19, 2013. AbbVie Inc. is the owner by assignment of the '952 Patent and has the right to sue for infringement thereof. AbbVie lists the '952 Patent in the Orange Book for NDA 21-906. A true and correct copy of the '952 Patent is attached as Exhibit F.

40. The '015 Patent was duly and legally issued by the PTO on March 19, 2013. AbbVie Inc. is the owner by assignment of the '015 Patent and has the right to sue for infringement thereof. AbbVie lists the '015 Patent in the Orange Book for NDA No. 21-906. A true and correct copy of the '015 Patent is attached as Exhibit G.

41. The '347 Patent was duly and legally issued by the PTO on June 25, 2013. AbbVie Deutschland GmbH & Co. KG is the owner by assignment of the '347 Patent and has the right to sue for infringement thereof. AbbVie lists the '347 Patent in the Orange Book for NDA No. 21-906. A true and correct copy of the '347 Patent is attached as Exhibit H.

42. The '878 Patent was duly and legally issued by the PTO on April 8, 2014. AbbVie Inc. is the owner by assignment of the '878 Patent and has the right to sue for infringement thereof. AbbVie lists the '878 Patent in the Orange Book for NDA 21-906. A true and correct copy of the '878 Patent is attached as Exhibit I.

FIRST COUNT
FOR PATENT INFRINGEMENT OF THE '359 PATENT

43. Paragraphs 1–42 are incorporated herein by reference.

44. On information and belief, Defendants acted in concert to file and have maintained ANDA No. 090-371 in order to obtain approval to manufacture, use, offer to sell, and

sell Cipla's Generic Lopinavir/Ritonavir Tablets in the United States before the expiration of the '359 Patent.

45. On information and belief, Defendants acted in concert to file with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '359 Patent are purportedly invalid and/or not infringed.

46. On information and belief, Cipla has represented to the FDA in Cipla's ANDA No. 090-371 that Cipla's Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

47. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 090-371 seeking approval for the commercial manufacture, use, or sale of Cipla's Generic Lopinavir/Ritonavir Tablets before the expiration date of the '359 Patent constitutes infringement of one or more claims of the '359 Patent, either literally or under the doctrine of equivalents.

48. Based on information and belief, including based on a review of Cipla's Notice Letter, Defendants will infringe, under § 271(a), either literally or under the doctrine of equivalents, at least independent claim 1 and dependent claim 8 of the '359 patent. Upon information and belief, including based on a review of Cipla's Notice Letter, which, *inter alia*, (1) does not contest that Cipla's Generic Lopinavir/Ritonavir Tablets contain amorphous ritonavir, (2) further does not contest that amorphous ritonavir in Cipla's Generic Lopinavir/Ritonavir Tablets is substantially pure; and (3) indicates that Cipla's Generic Lopinavir/Ritonavir Tablets are in the form of a solid dispersion of amorphous ritonavir, a solid solution or a glassy solution and are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets, Cipla's Generic Lopinavir/Ritonavir

Tablets comprise “substantially pure amorphous ritonavir” as that term is properly construed and as required by claim 1. On information and belief, including Cipla’s failure to contest infringement of any remaining limitations of claim 1, Cipla’s Generic Lopinavir/Ritonavir Tablets satisfy any remaining limitations of claim 1. Upon information and belief, Cipla’s Generic Lopinavir/Ritonavir Tablets comprise substantially pure amorphous ritonavir that “does not contain more than about 10% of any other compound” as required by claim 1 and as further required by claim 8. On information and belief, including Cipla’s failure to contest infringement of the remaining limitations of claim 8, Cipla’s Generic Lopinavir/Ritonavir Tablets satisfy the remaining limitations of claim 8. For at least these reasons, on information and belief, Defendants will infringe under § 271(a) at least claims 1 and 8 of the ’359 patent, either literally or under the doctrine of equivalents, by making, selling, offering to sell, and/or importing Cipla’s Generic Lopinavir/Ritonavir Tablets.

49. AbbVie will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import their Cipla’s Generic Lopinavir/Ritonavir Tablets in or into the United States, and are not enjoined from doing so. Pursuant to 35 U.S.C. §§ 271(e)(4) and/or 283, AbbVie is entitled to an order that the effective date of any approval of ANDA No. 090-371 for Cipla’s Generic Lopinavir/Ritonavir Tablets shall be a date which is not earlier than the date of expiration of the ’359 Patent (and any additional dates of exclusivity), and an injunction against such infringement. AbbVie does not have an adequate remedy at law.

SECOND COUNT
FOR PATENT INFRINGEMENT OF THE ’752 PATENT

50. Paragraphs 1–49 are incorporated herein by reference.

51. On information and belief, Defendants acted in concert to file and have maintained ANDA No. 090-371 in order to obtain approval to manufacture, use, offer to sell, and

sell Cipla's Generic Lopinavir/Ritonavir Tablets in the United States before the expiration of the '752 Patent.

52. On information and belief, Defendants acted in concert to file with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '752 Patent are purportedly invalid and/or not infringed.

53. On information and belief, Cipla has represented to the FDA in Cipla's ANDA No. 090-371 that Cipla's Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

54. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 090-371 seeking approval for the commercial manufacture, use, or sale of Cipla's Generic Lopinavir/Ritonavir Tablets before the expiration date of the '752 Patent constitutes infringement of one or more claims of the '752 patent, either literally or under the doctrine of equivalents.

55. Under 35 U.S.C. §§ 271(b) and (e)(2)(A), the submission to the FDA of ANDA No. 090-371 seeking approval for the commercial manufacture, use, or sale of Cipla's Generic Lopinavir/Ritonavir Tablets before the expiration date of the '752 Patent constitutes induced infringement of one or more claims of the '752 Patent, either literally or under the doctrine of equivalents.

56. On information and belief, Defendants are actively seeking FDA approval to sell Cipla's Generic Lopinavir/Ritonavir Tablets for the same indication, the same dosages, and the same method of use as the Kaletra® products sold by AbbVie.

57. On information and belief, Defendants' offering to sell, sale, making, and/or importation of Cipla's Generic Lopinavir/Ritonavir Tablets, once ANDA No. 090-371 is

approved by the FDA, would actively induce infringement of at least one of the claims of the '752 Patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

58. Defendants have knowledge and are aware of AbbVie's '752 Patent, as evidenced by Cipla's Notice Letter.

59. On information and belief, by the filing of ANDA No. 090-371 with a proposed package insert having directions that encourage patients to administer Cipla's Generic Lopinavir/Ritonavir Tablets to treat an HIV infection, Defendants have an affirmative intent to actively induce infringement by patients of one or more claims of the '752 Patent, either literally or under the doctrine of equivalents.

60. On information and belief, by the filing of ANDA No. 090-371 with a proposed package insert having directions that encourage medical practitioners to administer Cipla's Generic Lopinavir/Ritonavir Tablets to treat an HIV infection, Defendants have an affirmative intent to actively induce infringement by medical practitioners of one or more claims of the '752 Patent, either literally or under the doctrine of equivalents.

61. On information and belief, Defendants are aware and intend that patients will administer Cipla's Generic Lopinavir/Ritonavir Tablets and directly infringe at least one claim of the '752 Patent, either literally or under the doctrine of equivalents.

62. On information and belief, Defendants are aware and intend that medical practitioners will administer Cipla's Generic Lopinavir/Ritonavir Tablets and directly infringe at least one claim of the '752 Patent, either literally or under the doctrine of equivalents.

63. On information and belief, Defendants are aware and intend that patients will administer Cipla's Generic Lopinavir/Ritonavir Tablets in a method of treatment according to the directions and instructions in the proposed package insert that will directly infringe at least one

claim of the '752 Patent, either literally or under the doctrine of equivalents.

64. On information and belief, Defendants are aware and intend that medical practitioners will administer Cipla's Generic Lopinavir/Ritonavir Tablets in a method of treatment according to the directions and instructions in the proposed package insert that will directly infringe at least one claim of the '752 Patent, either literally or under the doctrine of equivalents.

65. On information and belief, Defendants know that they will aid and abet another's direct infringement of at least one of the claims of the '752 Patent, either literally or under the doctrine of equivalents, by Defendants' proposed package insert for Cipla's Generic Lopinavir/Ritonavir Tablets.

66. On information and belief, therefore, Defendants' offering to sell, sale, making, and/or importation of Cipla's Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would actively, intentionally, and knowingly induce infringement of one or more claims of the '752 Patent, either literally or under the doctrine of equivalents.

67. On information and belief, Cipla's Generic Lopinavir/Ritonavir Tablets, if approved by the FDA, will be imported by Defendants into the United States, offered for sale, and sold in the United States by them or on their behalf, and will be administered by patients in the United States, and will be administered by medical practitioners in the United States, which will constitute separate acts of direct infringement of at least one claim under 35 U.S.C. § 271(a) of the '752 Patent by Cipla, patients, and medical practitioners. On information and belief, the administration of Cipla's Generic Lopinavir/Ritonavir Tablets will occur with Defendants' specific intent and encouragement, and will be conduct that Defendants know will occur. On information and belief, Defendants will actively induce, encourage, aid, and abet that conduct by

patients or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of AbbVie's rights under the '752 Patent.

68. Defendants' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Cipla's Generic Lopinavir/Ritonavir Tablets will infringe one or more claims of the '752 Patent under § 271(b), either literally or under the doctrine of equivalents.

69. Based on information and belief, including based on a review of Cipla's Notice Letter, Defendants will infringe, under § 271(a), either literally or under the doctrine of equivalents, at least claim 8 and will induce infringement, under § 271(b), either literally or under the doctrine of equivalents, at least dependent claim 38 of the '752 patent. Cipla's Generic Lopinavir/Ritonavir Tablets are a "pharmaceutical composition comprising ritonavir," as required by claim 1, from which claim 8 depends. On information and belief, Cipla's Generic Lopinavir/Ritonavir Tablets satisfy the remaining limitations of claim 1. In addition, on information and belief, Cipla's Generic Lopinavir/Ritonavir Tablets meet all remaining limitations of claim 8. On information and belief, Cipla's Generic Lopinavir/Ritonavir Tablets will be approved for the same indication as Kaletra®, and such approved use will meet the requirement that the Tablets be used in a "method of treating an HIV infection," as required by claim 38. Cipla's Generic Lopinavir/Ritonavir Tablets further comprise ABT-378 ("lopinavir"), as required by claim 6, from which claim 38 depends. On information and belief, Cipla's Generic Lopinavir/Ritonavir Tablets satisfy all remaining limitations of claim 6, from which claim 38 depends. Upon information and belief, upon FDA approval of Cipla's Generic Lopinavir/Ritonavir Tablets, medical practitioners will administer the Generic Lopinavir/Ritonavir Tablets to humans (mammals) in order to treat an HIV infection in accordance with and pursuant to the directions in Cipla's product labeling for its Generic

Lopinavir/Ritonavir Tablets, and at least such medical practitioners will thus directly infringe claim 10, from which claim 38 depends. Upon information and belief, Cipla's Generic Lopinavir/Ritonavir Tablets satisfy the remaining limitations of claim 38. Upon information and belief, the use of Cipla's Generic Lopinavir/Ritonavir Tablets by at least such medical practitioners will directly infringe claim 38. For at least the reasons discussed in more detail above, upon information and belief, Cipla knowingly and intentionally will induce medical practitioners to infringe claim 38. Upon information and belief, Cipla will also knowingly and intentionally induce patients to infringe claim 38.

70. In its Notice Letter, Cipla did not assert any basis for noninfringement for any claim of the '752 patent.

71. For at least these reasons, on information and belief, Defendants will infringe under § 271(a) and (b) at least claims 8 and 38 of the '752 patent, either literally or under the doctrine of equivalents, by making, selling, offering to sell, or inducing others to use Cipla's Generic Lopinavir/Ritonavir Tablets.

72. AbbVie will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import Cipla's Generic Lopinavir/Ritonavir Tablets in or into the United States, and is not enjoined from doing so. Pursuant to 35 U.S.C. §§ 271(e)(4) and/or 283, AbbVie is entitled to an order that the effective date of any approval of ANDA No. 090-371 for Cipla's Generic Lopinavir/Ritonavir Tablets shall be a date which is not earlier than the date of expiration of the '752 Patent (and any additional dates of exclusivity), and an injunction against such infringement. AbbVie does not have an adequate remedy at law.

THIRD COUNT
FOR PATENT INFRINGEMENT OF THE '899 PATENT

73. Paragraphs 1–72 are incorporated herein by reference.

74. On information and belief, Defendants acted in concert to file and have maintained ANDA No. 090-371 in order to obtain approval to manufacture, use, offer to sell, and sell Cipla's Generic Lopinavir/Ritonavir Tablets in the United States before the expiration of the '899 Patent.

75. On information and belief, Defendants acted in concert to file with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '899 Patent are purportedly invalid and/or not infringed.

76. On information and belief, Cipla has represented to the FDA in Cipla's ANDA No. 090-371 that Cipla's Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

77. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 090-371 seeking approval for the commercial manufacture, use, or sale of Cipla's Generic Lopinavir/Ritonavir Tablets before the expiration date of the '899 Patent constitutes infringement of one or more claims of the '899 Patent, either literally or under the doctrine of equivalents.

78. Based on information and belief, including based on a review of Cipla's Notice Letter, Defendants will infringe, under § 271(a), either literally or under the doctrine of equivalents, at least independent claim 1 and dependent claim 4 of the '899 Patent. Cipla's Generic Lopinavir/Ritonavir Tablets are a "solid pharmaceutical dosage form" that contains lopinavir and ritonavir as required by claim 1. On information and belief, Cipla's Generic Lopinavir/Ritonavir Tablets meet all remaining limitations of claim 1. On information and belief, Cipla's Generic Lopinavir/Ritonavir Tablets also satisfy all the further limitations of claim 4.

79. In its Notice Letter, Cipla did not assert any basis for noninfringement for any

claim of the '899 Patent.

80. For at least these reasons, on information and belief, Defendants will infringe under § 271(a) at least claims 1 and 4 of the '899 patent, either literally or under the doctrine of equivalents, by making, selling, offering to sell, and/or importing Cipla's Generic Lopinavir/Ritonavir Tablets.

81. AbbVie will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import Cipla's Generic Lopinavir/Ritonavir Tablets in or into the United States, and are not enjoined from doing so. Pursuant to 35 U.S.C. §§ 271(e)(4) and/or 283, AbbVie is entitled to an order that the effective date of any approval of ANDA No. 090-371 for Cipla's Generic Lopinavir/Ritonavir Tablets shall be a date which is not earlier than the date of expiration of the '899 Patent (and any additional dates of exclusivity), and an injunction against such infringement. AbbVie does not have an adequate remedy at law.

FOURTH COUNT
FOR PATENT INFRINGEMENT OF THE '349 PATENT

82. Paragraphs 1–81 are incorporated herein by reference.

83. On information and belief, Defendants acted in concert to file and have maintained ANDA No. 090-371 in order to obtain approval to manufacture, use, offer to sell, and sell Cipla's Generic Lopinavir/Ritonavir Tablets in the United States before the expiration of the '349 Patent.

84. On information and belief, Defendants filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '349 Patent are purportedly invalid and/or not infringed.

85. On information and belief, Cipla has represented to the FDA in Cipla's ANDA No. 090-371 that Cipla's Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically

equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

86. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 090-371 seeking approval for the commercial manufacture, use, or sale of Cipla's Generic Lopinavir/Ritonavir Tablets before the expiration date of the '349 Patent constitutes infringement of one or more claims of the '349 Patent, either literally or under the doctrine of equivalents.

87. Based on information and belief, including based on a review of Cipla's Notice Letter, Defendants will infringe, under § 271(a), either literally or under the doctrine of equivalents, at least independent claim 1 and dependent claim 6 of the '349 Patent. Cipla's Generic Lopinavir/Ritonavir Tablets are a "solid pharmaceutical dosage form" that contains ritonavir as required by claim 1. On information and belief, Cipla's Generic Lopinavir/Ritonavir Tablets meet all additional limitations of claim 1. On information and belief, Cipla's Generic Lopinavir/Ritonavir Tablets also satisfy all the further limitations of claim 6.

88. In its Notice Letter, Cipla did not assert any basis for noninfringement for any claim of the '349 Patent.

89. For at least these reasons, on information and belief, Defendants will infringe under § 271(a) at least claims 1 and 6 of the '349 patent, either literally or under the doctrine of equivalents, by making, selling, offering to sell, and/or importing Cipla's Generic Lopinavir/Ritonavir Tablets.

90. AbbVie will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import Cipla's Generic Lopinavir/Ritonavir Tablets in or into the United States, and are not enjoined from doing so. Pursuant to 35 U.S.C. §§ 271(e)(4) and/or 283, AbbVie is entitled to an order that the effective date of any approval of ANDA No. 090-371 for

Cipla's Generic Lopinavir/Ritonavir Tablets shall be a date which is not earlier than the date of expiration of the '349 Patent (and any additional dates of exclusivity), and an injunction against such infringement. AbbVie does not have an adequate remedy at law.

FIFTH COUNT
FOR PATENT INFRINGEMENT OF THE '613 PATENT

91. Paragraphs 1–90 are incorporated herein by reference.
92. On information and belief, Defendants acted in concert to file and have maintained ANDA No. 090-371 in order to obtain approval to manufacture, use, offer to sell, and sell Cipla's Generic Lopinavir/Ritonavir Tablets in the United States before the expiration of the '613 Patent.
93. On information and belief, Defendants acted in concert to file with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '613 Patent are purportedly invalid and/or not infringed.
94. On information and belief, Cipla has represented to the FDA in Cipla's ANDA No. 090-371 that Cipla's Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.
95. Under 35 U.S.C. §§ 271(b) and (e)(2)(A), the submission to the FDA of ANDA No. 090-371 seeking approval for the commercial manufacture, use, or sale of Cipla's Generic Lopinavir/Ritonavir Tablets before the expiration date of the '613 Patent constitutes induced infringement of one or more claims of the '613 Patent, either literally or under the doctrine of equivalents.
96. On information and belief, Defendants are actively seeking FDA approval to sell Cipla's Generic Lopinavir/Ritonavir Tablets for the same indication, the same dosages, and the same method of use as the Kaletra® products sold by AbbVie.

97. On information and belief, Defendants' offering to sell, sale, making, and/or importation of Cipla's Generic Lopinavir/Ritonavir Tablets, once ANDA No. 090-371 is approved by the FDA, would actively induce infringement of at least one of the claims of the '613 Patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

98. Defendants have knowledge and are aware of AbbVie's '613 Patent, as evidenced by Cipla's Notice Letter.

99. On information and belief, by the filing of ANDA No. 090-371 with a proposed package insert having directions that encourage patients to administer Cipla's Generic Lopinavir/Ritonavir Tablets to treat an HIV infection, Defendants have an affirmative intent to actively induce infringement by patients of one or more claims of the '613 Patent, either literally or under the doctrine of equivalents.

100. On information and belief, by the filing of ANDA No. 090-371 with a proposed package insert having directions that encourage medical practitioners to administer Cipla's Generic Lopinavir/Ritonavir Tablets to treat an HIV infection, Defendants have an affirmative intent to actively induce infringement by medical practitioners of one or more claims of the '613 Patent, either literally or under the doctrine of equivalents.

101. On information and belief, Defendants are aware and intend that patients will administer Cipla's Generic Lopinavir/Ritonavir Tablets and directly infringe at least one claim of the '613 Patent, either literally or under the doctrine of equivalents.

102. On information and belief, Defendants are aware and intend that medical practitioners will administer Cipla's Generic Lopinavir/Ritonavir Tablets and directly infringe at least one claim of the '613 Patent, either literally or under the doctrine of equivalents.

103. On information and belief, Defendants are aware and intend that patients will

administer Cipla's Generic Lopinavir/Ritonavir Tablets in a method of treatment according to the directions and instructions in the proposed package insert that will directly infringe at least one claim of the '613 Patent, either literally or under the doctrine of equivalents.

104. On information and belief, Defendants are aware and intend that medical practitioners will administer Cipla's Generic Lopinavir/Ritonavir Tablets in a method of treatment according to the directions and instructions in the proposed package insert that will directly infringe at least one claim of the '613 Patent, either literally or under the doctrine of equivalents.

105. On information and belief, Defendants know that they will aid and abet another's direct infringement of at least one of the claims of the '613 Patent, either literally or under the doctrine of equivalents, by Defendants' proposed package insert for Cipla's Generic Lopinavir/Ritonavir Tablets.

106. On information and belief, therefore, Defendants' offering to sell, sale, making, and/or importation of Cipla's Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would actively, intentionally, and knowingly induce infringement of one or more claims of the '613 Patent, either literally or under the doctrine of equivalents.

107. On information and belief, Cipla's Generic Lopinavir/Ritonavir Tablets, if approved by the FDA, will be administered by patients in the United States, and will be administered by medical practitioners in the United States, which will constitute separate acts of direct infringement of at least one claim under 35 U.S.C. § 271(a) of the '613 Patent by patients and medical practitioners. On information and belief, the administration, and prescription of Cipla's Generic Lopinavir/Ritonavir Tablets will occur with Defendants' specific intent and encouragement, and will be conduct that Defendants know will occur. On information and belief,

Defendants will actively induce, encourage, aid, and abet that conduct by patients or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of AbbVie's rights under the '613 Patent.

108. Defendants' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Cipla's Generic Lopinavir/Ritonavir Tablets will infringe one or more claims of the '613 Patent under § 271(b), either literally or under the doctrine of equivalents.

109. Based on information and belief, including based on a review of Cipla's Notice Letter, Defendants will induce infringement under § 271(b), either literally or under the doctrine of equivalents, of at least independent claim 1 and dependent claim 3 of the '613 Patent. On information and belief, Cipla's Generic Lopinavir/Ritonavir Tablets will be approved for the same indication as Kaletra®, and such approved use will meet the requirement that the Tablets be used in a "method of treating an HIV infection," as required by claim 1. Cipla's Generic Lopinavir/Ritonavir Tablets are "solid pharmaceutical dosage form[s]" that comprise lopinavir and ritonavir, as required by claim 1. On information and belief, Cipla's Generic Lopinavir/Ritonavir Tablets satisfy all remaining limitations of claim 1. Upon information and belief, upon FDA approval of Cipla's Generic Lopinavir/Ritonavir Tablets, medical practitioners will administer the Generic Lopinavir/Ritonavir Tablets to humans (mammals) in order to treat an HIV infection in accordance with and pursuant to the directions in Cipla's product labeling for its Generic Lopinavir/Ritonavir Tablets, and will thus directly infringe claim 1. On information and belief, Cipla's Generic Lopinavir/Ritonavir Tablets satisfy all further limitations of claim 3. Upon information and belief, the use of Cipla's Generic Lopinavir/Ritonavir Tablets by medical practitioners is performed in such a manner that the Tablets satisfy the further limitations of claim 3, and at least such medical practitioners will directly infringe claims 1 and

3. For at least the reasons discussed in more detail above, upon information and belief, Cipla knowingly and intentionally will induce at least such medical practitioners to infringe claims 1 and 3. Upon information and belief, Cipla will also knowingly and intentionally induce patients to infringe claims 1 and 3.

110. In its Notice Letter, Cipla did not assert any basis for noninfringement for any claim of the '613 Patent.

111. For at least these reasons, on information and belief, Defendants will induce infringement under § 271(b) by inducing others to use Cipla's Generic Lopinavir/Ritonavir Tablets.

112. AbbVie will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import Cipla's Generic Lopinavir/Ritonavir Tablets in or into the United States, and is not enjoined from doing so. Pursuant to 35 U.S.C. §§ 271(e)(4) and/or 283, AbbVie is entitled to an order that the effective date of any approval of ANDA No. 090-371 for Cipla's Generic Lopinavir/Ritonavir Tablets shall be a date which is not earlier than the date of expiration of the '613 Patent (and any additional dates of exclusivity), and an injunction against such infringement. AbbVie does not have an adequate remedy at law.

SIXTH COUNT
FOR PATENT INFRINGEMENT OF THE '952 PATENT

113. Paragraphs 1–112 are incorporated herein by reference.

114. On information and belief, Defendants acted in concert to file and have maintained ANDA No. 090-371 in order to obtain approval to manufacture, use, offer to sell, and sell Cipla's Generic Lopinavir/Ritonavir Tablets in the United States before the expiration of the '952 Patent.

115. On information and belief, Defendants acted in concert to file with the FDA,

pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '952 Patent are purportedly invalid and/or not infringed.

116. On information and belief, Cipla has represented to the FDA in Cipla's ANDA No. 090-371 that Cipla's Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

117. Under 35 U.S.C. §§ 271(e)(2)(A), the submission to the FDA of ANDA No. 090-371 seeking approval for the commercial manufacture, use, or sale of Cipla's Generic Lopinavir/Ritonavir Tablets before the expiration date of the '952 Patent constitutes infringement of one or more claims of the '952 Patent, either literally or under the doctrine of equivalents.

118. Under 35 U.S.C. §§ 271(b) and (e)(2)(A), the submission to the FDA of ANDA No. 090-371 seeking approval for the commercial manufacture, use, or sale of Cipla's Generic Lopinavir/Ritonavir Tablets before the expiration date of the '952 Patent constitutes induced infringement of one or more claims of the '952 Patent, either literally or under the doctrine of equivalents.

119. On information and belief, Defendants are actively seeking FDA approval to sell Cipla's Generic Lopinavir/Ritonavir Tablets for the same indication, the same dosages, and the same method of use as the Kaletra® products sold by AbbVie.

120. On information and belief, Defendants' offering to sell, sale, making, and/or importation of Cipla's Generic Lopinavir/Ritonavir Tablets, once ANDA No. 090-371 is approved by the FDA, would actively induce infringement of at least one of the claims of the '952 Patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

121. Defendants have knowledge and are aware of AbbVie's '952 Patent, as evidenced

by Cipla's Notice Letter.

122. On information and belief, by the filing of ANDA No. 090-371 with a proposed package insert having directions that encourage patients to administer Cipla's Generic Lopinavir/Ritonavir Tablets to treat HIV, Defendants have an affirmative intent to actively induce infringement by patients of one or more claims of the '952 Patent, either literally or under the doctrine of equivalents.

123. On information and belief, by the filing of ANDA No. 090-371 with a proposed package insert having directions that encourage medical practitioners to administer Cipla's Generic Lopinavir/Ritonavir Tablets to treat HIV, Defendants have an affirmative intent to actively induce infringement by medical practitioners of one or more claims of the '952 Patent, either literally or under the doctrine of equivalents.

124. On information and belief, Defendants are aware and intend that patients will administer Cipla's Generic Lopinavir/Ritonavir Tablets and directly infringe at least one claim of the '952 Patent, either literally or under the doctrine of equivalents.

125. On information and belief, Defendants are aware and intend that medical practitioners will administer Cipla's Generic Lopinavir/Ritonavir Tablets and direct and control patients to take Cipla's Generic Lopinavir/Ritonavir Tablets in a way that will directly infringe at least one claim of the '952 Patent, either literally or under the doctrine of equivalents.

126. On information and belief, Defendants are aware and intend that patients will administer Cipla's Generic Lopinavir/Ritonavir Tablets in a method of treatment according to the directions and instructions in the proposed package insert that will directly infringe at least one claim of the '952 Patent, either literally or under the doctrine of equivalents.

127. On information and belief, Defendants are aware and intend that medical

practitioners will administer Cipla's Generic Lopinavir/Ritonavir Tablets and direct patients to take them in a method of treatment according to the directions and instructions in the proposed package insert that will directly infringe at least one claim of the '952 Patent, either literally or under the doctrine of equivalents.

128. On information and belief, Defendants know that they will aid and abet another's direct infringement of at least one of the claims of the '952 Patent, either literally or under the doctrine of equivalents, by Defendants' proposed package insert for Cipla's Generic Lopinavir/Ritonavir Tablets.

129. On information and belief, therefore, Defendants' offering to sell, sale, making, and/or importation of Cipla's Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would actively, intentionally, and knowingly induce infringement of one or more claims of the '952 Patent, either literally or under the doctrine of equivalents.

130. On information and belief, Cipla's Generic Lopinavir/Ritonavir Tablets, if approved by the FDA, will be administered by patients in the United States, and will be administered by medical practitioners in the United States, which will constitute separate acts of direct infringement of at least one claim under 35 U.S.C. § 271(a) of the '952 Patent by patients or medical practitioners. On information and belief, the administration of Cipla's Generic Lopinavir/Ritonavir Tablets will occur with Defendants' specific intent and encouragement, and will be conduct that Defendants know will occur. On information and belief, Defendants will actively induce, encourage, aid, and abet that conduct by patients or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of AbbVie's rights under the '952 Patent.

131. Defendants' threatened actions in actively aiding, abetting, encouraging, and

inducing sales of Cipla's Generic Lopinavir/Ritonavir Tablets will infringe one or more claims of the '952 Patent under § 271(b), either literally or under the doctrine of equivalents.

132. Based on information and belief, including based on a review of Cipla's Notice Letter, Defendants will induce infringement, under § 271(b), either literally or under the doctrine of equivalents, of at least independent claim 1 and dependent claim 2 of the '952 Patent. On information and belief, Cipla's Generic Lopinavir/Ritonavir Tablets will be approved for the same indication as Kaletra®, and such approved use will meet the requirement that the Tablets be used in a "method of treating HIV," as required by claim 1. On information and belief, medical practitioners will control and direct patients to take Cipla's Generic Lopinavir/Ritonavir Tablets "without food or under a fasting condition," as required by claim 1. Cipla's Generic Lopinavir/Ritonavir Tablets are a "solid pharmaceutical dosage form" that contains lopinavir and ritonavir as required by claim 1. On information and belief, Cipla's Generic Lopinavir/Ritonavir Tablets satisfy all remaining limitations of claim 1. Upon information and belief, upon FDA approval of Cipla's Generic Lopinavir/Ritonavir Tablets, medical practitioners will administer the Generic Lopinavir/Ritonavir Tablets to humans (mammals) in order to treat an HIV infection in accordance with and pursuant to the directions in Cipla's product labeling for its Generic Lopinavir/Ritonavir Tablets, and will thus directly infringe claim 1. Upon information and belief, Cipla's Generic Lopinavir/Ritonavir Tablets satisfy the further limitations of claim 2. Upon information and belief, the use of Cipla's Generic Lopinavir/Ritonavir Tablets by medical practitioners is performed in such a manner to satisfy all remaining limitations of claim 2, and at least such medical practitioners will directly infringe claims 1 and 2. For at least the reasons discussed in more detail above, upon information and belief, Cipla knowingly and intentionally will induce at least such medical practitioners to infringe claims 1 and 2. Upon information and

belief, Cipla will also knowingly and intentionally induce patients to infringe claims 1 and 2.

133. In its Notice Letter, Cipla did not assert any basis for noninfringement for claims 1 and 2 of the '952 Patent.

134. For at least these reasons, on information and belief, Defendants will induce infringement under § 271(b) by inducing others to use Cipla's Generic Lopinavir/Ritonavir Tablets.

135. AbbVie will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import Cipla's Generic Lopinavir/Ritonavir Tablets in or into the United States, and is not enjoined from doing so. Pursuant to 35 U.S.C. §§ 271(e)(4) and/or 283, AbbVie is entitled to an order that the effective date of any approval of ANDA No. 090-371 for Cipla's Generic Lopinavir/Ritonavir Tablets shall be a date which is not earlier than the date of expiration of the '952 Patent (and any additional dates of exclusivity), and an injunction against such infringement. AbbVie does not have an adequate remedy at law.

SEVENTH COUNT
FOR PATENT INFRINGEMENT OF THE '015 PATENT

136. Paragraphs 1–135 are incorporated herein by reference.

137. On information and belief, Defendants acted in concert to file and have maintained ANDA No. 090-371 in order to obtain approval to manufacture, use, offer to sell, and sell Cipla's Generic Lopinavir/Ritonavir Tablets in the United States before the expiration of the '015 Patent.

138. On information and belief, Defendants filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '015 Patent are purportedly invalid and/or not infringed.

139. On information and belief, Cipla has represented to the FDA in Cipla's ANDA

No. 090-371 that Cipla's Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

140. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 090-371 seeking approval for the commercial manufacture, use, or sale of Cipla's Generic Lopinavir/Ritonavir Tablets before the expiration date of the '015 Patent constitutes infringement of one or more claims of the '015 Patent, either literally or under the doctrine of equivalents.

141. Based on information and belief, including based on a review of Cipla's Notice Letter, Defendants will infringe, under § 271(a), either literally or under the doctrine of equivalents, at least independent claim 1 and dependent claim 4 of the '015 patent. Cipla's Generic Lopinavir/Ritonavir Tablets are a "solid pharmaceutical dosage form" that contains lopinavir and ritonavir, as required by claim 1. On information and belief, Cipla's Generic Lopinavir/Ritonavir Tablets meet all remaining limitations of claim 1. On information and belief, Cipla's Generic Lopinavir/Ritonavir Tablets satisfy all the further limitations of claim 4.

142. In its Notice Letter, Cipla did not assert any basis for noninfringement for any claim of the '015 Patent.

143. For at least these reasons, on information and belief, Defendants will infringe under § 271(a) at least claims 1 and 4 of the '015 patent, either literally or under the doctrine of equivalents, by making, selling, offering to sell, and/or importing Cipla's Generic Lopinavir/Ritonavir Tablets.

144. AbbVie will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import Cipla's Generic Lopinavir/Ritonavir Tablets in or into the United States, and are not enjoined from doing so. Pursuant to 35 U.S.C. §§ 271(e)(4) and/or 283,

AbbVie is entitled to an order that the effective date of any approval of ANDA No. 090-371 for Cipla's Generic Lopinavir/Ritonavir Tablets shall be a date which is not earlier than the date of expiration of the '015 Patent (and any additional dates of exclusivity), and an injunction against such infringement. AbbVie does not have an adequate remedy at law.

EIGHTH COUNT
FOR PATENT INFRINGEMENT OF THE '347 PATENT

145. Paragraphs 1–144 are incorporated herein by reference.

146. On information and belief, Defendants acted in concert to file and have maintained ANDA No. 090-371 in order to obtain approval to manufacture, use, offer to sell, and sell Cipla's Generic Lopinavir/Ritonavir Tablets in the United States before the expiration of the '347 Patent.

147. On information and belief, Defendants filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '347 Patent are purportedly invalid and/or not infringed.

148. On information and belief, Cipla has represented to the FDA in Cipla's ANDA No. 090-371 that Cipla's Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

149. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 090-371 seeking approval for the commercial manufacture, use, or sale of Cipla's Generic Lopinavir/Ritonavir Tablets before the expiration date of the '347 Patent constitutes infringement of one or more claims of the '347 Patent, either literally or under the doctrine of equivalents.

150. Based on information and belief, including based on a review of Cipla's Notice Letter, Defendants will infringe, under § 271(a), either literally or under the doctrine of

equivalents, at least independent claim 1 and dependent claim 2 of the '347 patent. Cipla's Generic Lopinavir/Ritonavir Tablets are a solid formulation, as required by claim 1. On information and belief, including based on a review of Cipla's Notice Letter, which, *inter alia*, indicates Cipla does not have any non-infringement position with respect to the claims of the '347 patent, Cipla's Generic Lopinavir/Ritonavir Tablets have 4.17% ritonavir, 16.67% lopinavir, 71.16% copovidone, and 7% sorbitan monolaurate (weight percentages). On information and belief, including based on a review of Cipla's Notice Letter, Cipla's Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets, and thus Cipla's Generic Lopinavir/Ritonavir Tablets are a solid, self-emulsifying formulation wherein the formulation is essentially free of lipid and active pharmaceutical ingredient crystals, and contains between 6 and 60% by weight of a lipid component or its equivalents, as required by claim 1. On information and belief, including Cipla's failure to contest infringement of the remaining limitations of claim 1, Cipla's Generic Lopinavir/Ritonavir Tablets meet all remaining limitations of claim 1. On information and belief, including Cipla's failure to contest infringement of the remaining limitations of claim 2, Cipla's Generic Lopinavir/Ritonavir Tablets satisfy all the further limitations of claim 2. For at least these reasons, on information and belief, Defendants will infringe under § 271(a) at least claims 1 and 2 of the '347 patent, either literally or under the doctrine of equivalents, by making, selling, offering to sell and/or importing Cipla's Generic Lopinavir/Ritonavir Tablets.

151. AbbVie will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import Cipla's Generic Lopinavir/Ritonavir Tablets in or into the United States, and are not enjoined from doing so. Pursuant to 35 U.S.C. §§ 271(e)(4) and/or 283, AbbVie is entitled to an order that the effective date of any approval of ANDA No. 090-371 for

Cipla's Generic Lopinavir/Ritonavir Tablets shall be a date which is not earlier than the date of expiration of the '347 Patent (and any additional dates of exclusivity), and an injunction against such infringement. AbbVie does not have an adequate remedy at law.

NINTH COUNT
FOR PATENT INFRINGEMENT OF THE '878 PATENT

152. Paragraphs 1–151 are incorporated herein by reference.

153. On information and belief, Defendants acted in concert to file and have maintained ANDA No. 090-371 in order to obtain approval to manufacture, use, offer to sell, and sell Cipla's Generic Lopinavir/Ritonavir Tablets in the United States before the expiration of the '878 Patent.

154. On information and belief, Defendants filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '878 Patent are purportedly invalid and/or not infringed.

155. On information and belief, Cipla has represented to the FDA in Cipla's ANDA No. 090-371 that Cipla's Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

156. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 090-371 seeking approval for the commercial manufacture, use, or sale of Cipla's Generic Lopinavir/Ritonavir Tablets before the expiration date of the '878 Patent constitutes infringement of one or more claims of the '878 Patent, either literally or under the doctrine of equivalents.

157. Under 35 U.S.C. §§ 271(b) and (e)(2)(A), the submission to the FDA of ANDA No. 090-371 seeking approval for the commercial manufacture, use, or sale of Cipla's Generic Lopinavir/Ritonavir Tablets before the expiration date of the '878 Patent constitutes induced

infringement of one or more claims of the '878 Patent, either literally or under the doctrine of equivalents.

158. On information and belief, Defendants are actively seeking FDA approval to sell Cipla's Generic Lopinavir/Ritonavir Tablets for the same indication, the same dosages, and the same method of use as the Kaletra® products sold by AbbVie.

159. On information and belief, Defendants' offering to sell, sale, making, and/or importation of Cipla's Generic Lopinavir/Ritonavir Tablets, once ANDA No. 090-371 is approved by the FDA, would actively induce infringement of at least one of the claims of the '878 Patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

160. Defendants have knowledge and are aware of AbbVie's '878 Patent, as evidenced by Cipla's Notice Letter.

161. On information and belief, by the filing of ANDA No. 090-371 with a proposed package insert having directions that encourage patients to administer Cipla's Generic Lopinavir/Ritonavir Tablets to treat HIV, Defendants have an affirmative intent to actively induce infringement by patients of one or more claims of the '878 Patent, either literally or under the doctrine of equivalents.

162. On information and belief, by the filing of ANDA No. 090-371 with a proposed package insert having directions that encourage medical practitioners to administer Cipla's Generic Lopinavir/Ritonavir Tablets to treat HIV, Defendants have an affirmative intent to actively induce infringement by medical practitioners of one or more claims of the '878 Patent, either literally or under the doctrine of equivalents.

163. On information and belief, Defendants are aware and intend that patients will administer and/or use Cipla's Generic Lopinavir/Ritonavir Tablets and directly infringe at least

one claim of the '878 Patent, either literally or under the doctrine of equivalents.

164. On information and belief, Defendants are aware and intend that medical practitioners will administer Cipla's Generic Lopinavir/Ritonavir Tablets and directly infringe at least one claim of the '878 Patent, either literally or under the doctrine of equivalents.

165. On information and belief, Defendants are aware and intend that patients will administer Cipla's Generic Lopinavir/Ritonavir Tablets in a method of treatment according to the directions and instructions in the proposed package insert that will directly infringe at least one claim of the '878 Patent, either literally or under the doctrine of equivalents.

166. On information and belief, Defendants are aware and intend that medical practitioners will administer Cipla's Generic Lopinavir/Ritonavir Tablets in a method of treatment according to the directions and instructions in the proposed package insert that will directly infringe at least one claim of the '878 Patent, either literally or under the doctrine of equivalents.

167. On information and belief, Defendants know that they will aid and abet another's direct infringement of at least one of the claims of the '878 Patent, either literally or under the doctrine of equivalents, by Defendants' proposed package insert for Cipla's Generic Lopinavir/Ritonavir Tablets.

168. On information and belief, therefore, Defendants' offering to sell, sale, making, and/or importation of Cipla's Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would actively, intentionally, and knowingly induce infringement of one or more claims of the '878 Patent, either literally or under the doctrine of equivalents.

169. On information and belief, Cipla's Generic Lopinavir/Ritonavir Tablets, if approved by the FDA, will be administered by patients in the United States, and will be

administered by medical practitioners in the United States, which will constitute separate acts of direct infringement of at least one claim under 35 U.S.C. § 271(a) of the '878 Patent by patients and medical practitioners. On information and belief, the administration of Cipla's Generic Lopinavir/Ritonavir Tablets will occur with Defendants' specific intent and encouragement, and will be conduct that Defendants know will occur. On information and belief, Defendants will actively induce, encourage, aid, and abet that conduct by patients or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of AbbVie's rights under the '878 Patent.

170. Defendants' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Cipla's Generic Lopinavir/Ritonavir Tablets will infringe one or more claims of the '878 Patent under § 271(b), either literally or under the doctrine of equivalents.

171. Based on information and belief, including based on a review of Cipla's Notice Letter, Defendants will induce infringement, under § 271(b), either literally or under the doctrine of equivalents, of at least independent claim 1 and dependent claim 2 of the '878 Patent. On information and belief, Cipla's Generic Lopinavir/Ritonavir Tablets will be approved for the same indication as Kaletra®, and such approved use will meet the requirement that the Tablets be used in a "method of treating HIV," as required by claim 1. Cipla's Generic Lopinavir/Ritonavir Tablets are a "solid pharmaceutical dosage form" that comprise ritonavir as required by claim 1. On information and belief, Cipla's Generic Lopinavir/Ritonavir Tablets satisfy all remaining limitations of claim 1. Upon information and belief, upon FDA approval of Cipla's Generic Lopinavir/Ritonavir Tablets, medical practitioners will administer the Generic Lopinavir/Ritonavir Tablets to humans (mammals) in order to treat an HIV infection in accordance with and pursuant to the directions in Cipla's product labeling for its Generic

Lopinavir/Ritonavir Tablets and will directly infringe claim 1. Upon information and belief, Cipla's Generic Lopinavir/Ritonavir Tablets satisfy all further limitations of claim 2. Upon information and belief, the use of Cipla's Generic Lopinavir/Ritonavir Tablets by medical practitioners will satisfy the further limitations of claim 2, and at least such medical practitioners will directly infringe claims 1 and 2. As discussed in more detail above, upon information and belief, Cipla knowingly and intentionally will induce such medical practitioners to infringe claims 1 and 2. Upon information and belief, Cipla will also knowingly and intentionally induce patients to infringe claims 1 and 2.

172. In its Notice Letter, Cipla did not assert any basis for noninfringement for any claim of the '878 Patent.

173. For at least these reasons, on information and belief, Defendants will induce infringement under § 271(a) by inducing others to use Cipla's Generic Lopinavir/Ritonavir Tablets.

174. AbbVie will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import Cipla's Generic Lopinavir/Ritonavir Tablets in or into the United States and is not enjoined from doing so. Pursuant to 35 U.S.C. §§ 271(e)(4) and/or 283, AbbVie is entitled to an order that the effective date of any approval of ANDA No. 090-371 for Cipla's Generic Lopinavir/Ritonavir Tablets shall be a date which is not earlier than the date of expiration of the '878 Patent (and any additional dates of exclusivity), and an injunction against such infringement. AbbVie does not have an adequate remedy at law.

TENTH COUNT
DECLARATORY JUDGMENT AS TO THE '359 PATENT

175. Paragraphs 1–174 are incorporated herein by reference.

176. On information and belief, Defendants are actively seeking FDA approval to sell

Cipla's Generic Lopinavir/Ritonavir Tablets for the same indication, the same dosages, and the same method of use as the Kaletra® products sold by AbbVie.

177. On information and belief, upon FDA approval of ANDA No. 090-371, Defendants will infringe one or more claims of the '359 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Cipla's Generic Lopinavir/Ritonavir Tablets, unless this Court orders that the effective date of any FDA approval of ANDA No. 090-371 shall be no earlier than the expiration date of the '359 Patent and any additional periods of exclusivity.

178. On information and belief, Defendants intend to commence sales of Cipla's Generic Lopinavir/Ritonavir Tablets immediately upon receiving final approval from the FDA.

179. On information and belief, in Cipla's ANDA No. 090-371, Cipla has represented to the FDA that Cipla's Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

180. On information and belief, therefore, Defendants' manufacture, importation, sale, and/or offer for sale of Cipla's Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would directly infringe one or more claims of the '359 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

181. Defendants have knowledge and are aware of AbbVie's '359 Patent, as evidenced by Cipla's Notice Letter.

182. A case or controversy exists between AbbVie and Defendants regarding the infringement and validity of the '359 Patent.

183. Under the totality of the circumstances, there is a substantial controversy between AbbVie and Defendants having sufficient immediacy and reality to establish declaratory

judgment jurisdiction relating to Defendants' threatened infringement of the '359 Patent.

184. AbbVie will be substantially and irreparably damaged and harmed by the infringing activities described above unless those activities are enjoined by this Court. AbbVie does not have an adequate remedy at law.

185. In view of the foregoing, there exists a substantial controversy between AbbVie and Cipla, which have adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ELEVENTH COUNT
DECLARATORY JUDGMENT AS TO THE '752 PATENT

186. Paragraphs 1–185 are incorporated herein by reference.

187. On information and belief, Defendants are actively seeking FDA approval to sell Cipla's Generic Lopinavir/Ritonavir Tablets for the same indication, the same dosages, and the same method of use as the Kaletra® products sold by AbbVie.

188. On information and belief, upon FDA approval of ANDA No. 090-371, Defendants will infringe one or more claims of the '752 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Cipla's Generic Lopinavir/Ritonavir Tablets, unless this Court orders that the effective date of any FDA approval of ANDA No. 090-371 shall be no earlier than the expiration date of the '752 Patent and any additional periods of exclusivity.

189. On information and belief, upon FDA approval of ANDA No. 090-371, Defendants will infringe one or more claims of the '752 Patent under 35 U.S.C. § 271(b), by actively inducing direct infringement by others (for example, by medical practitioners or patients), unless this Court orders that the effective date of any FDA approval of ANDA No. 090-371 shall be no earlier than the expiration date of the '752 Patent and any additional periods

of exclusivity.

190. On information and belief, Defendants intend to commence sales of Cipla's Generic Lopinavir/Ritonavir Tablets immediately upon receiving final approval from the FDA.

191. On information and belief, in Cipla's ANDA No. 090-371, Cipla has represented to the FDA that Cipla's Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

192. On information and belief, therefore, Defendants' manufacture, use, importation, sale, and/or offer for sale of Cipla's Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would directly infringe one or more claims of the '752 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

193. On information and belief, Defendants' offering to sell, sale, making, and/or importation of Cipla's Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would actively induce infringement under 35 U.S.C. § 271(b) of at least one of the claims of the '752 Patent, either literally or under the doctrine of equivalents.

194. A case or controversy exists between AbbVie and Defendants regarding the infringement and validity of the '752 Patent.

195. Under the totality of the circumstances, there is a substantial controversy between AbbVie and Defendants having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Defendants' threatened infringement of the '752 Patent.

196. AbbVie will be substantially and irreparably damaged and harmed by the infringing activities described above unless those activities are enjoined by this Court. AbbVie does not have an adequate remedy at law.

197. In view of the foregoing, there exists a substantial controversy between AbbVie

and Defendants, which have adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

TWELFTH COUNT
DECLARATORY JUDGMENT AS TO THE '899 PATENT

198. Paragraphs 1–187 are incorporated herein by reference.

199. On information and belief, Defendants are actively seeking FDA approval to sell Cipla's Generic Lopinavir/Ritonavir Tablets for the same indication, the same dosages, and the same method of use as the Kaletra® products sold by AbbVie.

200. On information and belief, upon FDA approval of ANDA No. 090-371, Defendants will infringe one or more claims of the '899 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Cipla's Generic Lopinavir/Ritonavir Tablets, unless this Court orders that the effective date of any FDA approval of ANDA No. 090-371 shall be no earlier than the expiration date of the '899 Patent and any additional periods of exclusivity.

201. On information and belief, Defendants intend to commence sales of Cipla's Generic Lopinavir/Ritonavir Tablets immediately upon receiving final approval from the FDA.

202. On information and belief, in Cipla's ANDA No. 090-371, Cipla has represented to the FDA that Cipla's Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

203. On information and belief, therefore, Defendants' manufacture, importation, sale, and/or offer for sale of Cipla's Generic Lopinavir/Ritonavir Tablets, once approved by the FDA would directly infringe one or more claims of the '899 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

204. Defendants have knowledge and are aware of AbbVie's '899 Patent, as evidenced

by Cipla's Notice Letter.

205. A case or controversy exists between AbbVie and Defendants regarding the infringement and validity of the '899 Patent.

206. Under the totality of the circumstances, there is a substantial controversy between AbbVie and Defendants having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Defendants' threatened infringement of the '899 Patent.

207. AbbVie will be substantially and irreparably damaged and harmed by the infringing activities described above unless those activities are enjoined by this Court. AbbVie does not have an adequate remedy at law.

208. In view of the foregoing, there exists a substantial controversy between AbbVie and Defendants, which have adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

THIRTEENTH COUNT
DECLARATORY JUDGMENT AS TO THE '349 PATENT

209. Paragraphs 1–208 are incorporated herein by reference.

210. On information and belief, Defendants are actively seeking FDA approval to sell Cipla's Generic Lopinavir/Ritonavir Tablets for the same indication, the same dosages, and the same method of use as the Kaletra® products sold by AbbVie.

211. On information and belief, upon FDA approval of ANDA No. 090-371, Defendants will infringe one or more claims of the '349 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Cipla's Generic Lopinavir/Ritonavir Tablets, unless this Court orders that the effective date of any FDA approval of ANDA No. 090-371 shall be no earlier than the expiration date of the '349 Patent and any additional periods of exclusivity.

212. On information and belief, Defendants intend to commence sales of Cipla's Generic Lopinavir/Ritonavir Tablets immediately upon receiving final approval from the FDA.

213. On information and belief, in Cipla's ANDA No. 090-371, Cipla has represented to the FDA that Cipla's Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

214. On information and belief, therefore, Defendants' manufacture, importation, sale, and/or offer for sale of Cipla's Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would directly infringe one or more claims of the '349 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

215. Defendants have knowledge and are aware of AbbVie's '349 Patent, as evidenced by Cipla's Notice Letter.

216. A case or controversy exists between AbbVie and Defendants regarding the infringement and validity of the '349 Patent.

217. Under the totality of the circumstances, there is a substantial controversy between AbbVie and Defendants having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Defendants' threatened infringement of the '349 Patent.

218. AbbVie will be substantially and irreparably damaged and harmed by the infringing activities described above unless those activities are enjoined by this Court. AbbVie does not have an adequate remedy at law.

219. In view of the foregoing, there exists a substantial controversy between AbbVie and Cipla, which have adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

FOURTEENTH COUNT
DECLARATORY JUDGMENT AS TO THE '613 PATENT

220. Paragraphs 1–219 are incorporated herein by reference.

221. On information and belief, Defendants are actively seeking FDA approval to sell Cipla's Generic Lopinavir/Ritonavir Tablets for the same indication, the same dosages, and the same method of use as the Kaletra® products sold by AbbVie.

222. On information and belief, upon FDA approval of ANDA No. 090-371, Defendants will infringe one or more claims of the '613 Patent under 35 U.S.C. § 271(b), by actively inducing direct infringement by others (for example, by medical practitioners or patients), unless this Court orders that the effective date of any FDA approval of ANDA No. 090-371 shall be no earlier than the expiration date of the '613 Patent and any additional periods of exclusivity.

223. On information and belief, Defendants intend to commence sales of Cipla's Generic Lopinavir/Ritonavir Tablets immediately upon receiving final approval from the FDA.

224. On information and belief, in Cipla's ANDA No. 090-371, Cipla has represented to the FDA that Cipla's Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

225. On information and belief, Defendants' offering to sell, sale, making, and/or importation of Cipla's Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would actively induce infringement under 35 U.S.C. § 271(b) of at least one of the claims of the '613 Patent, either literally or under the doctrine of equivalents.

226. Defendants have knowledge and are aware of AbbVie's '613 Patent, as evidenced by Cipla's Notice Letter.

227. A case or controversy exists between AbbVie and Defendants regarding the

infringement and validity of the '613 Patent.

228. Under the totality of the circumstances, there is a substantial controversy between AbbVie and Defendants having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Defendants' threatened infringement of the '613 Patent.

229. AbbVie will be substantially and irreparably damaged and harmed by the infringing activities described above unless those activities are enjoined by this Court. AbbVie does not have an adequate remedy at law.

230. In view of the foregoing, there exists a substantial controversy between AbbVie and Defendants, which have adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

FIFTEENTH COUNT
DECLARATORY JUDGMENT AS TO THE '952 PATENT

231. Paragraphs 1–230 are incorporated herein by reference.

232. On information and belief, Defendants are actively seeking FDA approval to sell Cipla's Generic Lopinavir/Ritonavir Tablets for the same indication, the same dosages, and the same method of use as the Kaletra® products sold by AbbVie.

233. On information and belief, upon FDA approval of ANDA No. 090-371, Defendants will infringe one or more claims of the '952 Patent under 35 U.S.C. § 271(b), by actively inducing direct infringement by others (for example, by medical practitioners or patients), unless this Court orders that the effective date of any FDA approval of ANDA No. 090-371 shall be no earlier than the expiration date of the '952 Patent and any additional periods of exclusivity.

234. On information and belief, Defendants intend to commence sales of Cipla's Generic Lopinavir/Ritonavir Tablets immediately upon receiving final approval from the FDA.

235. On information and belief, in Cipla's ANDA No. 090-371, Cipla has represented to the FDA that Cipla's Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

236. On information and belief, Defendants' offering to sell, sale, making, and/or importation of Cipla's Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would actively induce infringement under 35 U.S.C. § 271(b) of at least one of the claims of the '952 Patent, either literally or under the doctrine of equivalents.

237. Defendants have knowledge and are aware of AbbVie's '952 Patent, as evidenced by Cipla's Notice Letter.

238. A case or controversy exists between AbbVie and Defendants regarding the infringement and validity of the '952 Patent.

239. Under the totality of the circumstances, there is a substantial controversy between AbbVie and Defendants having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Defendants' threatened infringement of the '952 Patent.

240. AbbVie will be substantially and irreparably damaged and harmed by the infringing activities described above unless those activities are enjoined by this Court. AbbVie does not have an adequate remedy at law.

241. In view of the foregoing, there exists a substantial controversy between AbbVie and Defendants, which have adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

SIXTEENTH COUNT
DECLARATORY JUDGMENT AS TO THE '015 PATENT

242. Paragraphs 1–241 are incorporated herein by reference.

243. On information and belief, Defendants are actively seeking FDA approval to sell

Cipla's Generic Lopinavir/Ritonavir Tablets for the same indication, the same dosages, and the same method of use as the Kaletra® products sold by AbbVie.

244. On information and belief, upon FDA approval of ANDA No. 090-371, Defendants will infringe one or more claims of the '015 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Cipla's Generic Lopinavir/Ritonavir Tablets, unless this Court orders that the effective date of any FDA approval of ANDA No. 090-371 shall be no earlier than the expiration date of the '015 Patent and any additional periods of exclusivity.

245. On information and belief, Defendants intend to commence sales of Cipla's Generic Lopinavir/Ritonavir Tablets immediately upon receiving final approval from the FDA.

246. On information and belief, in Cipla's ANDA No. 090-371, Cipla has represented to the FDA that Cipla's Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

247. On information and belief, therefore, Defendants' manufacture, importation, sale, and/or offer for sale of Cipla's Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would directly infringe one or more claims of the '015 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

248. Defendants have knowledge and are aware of AbbVie's '015 Patent, as evidenced by Cipla's Notice Letter.

249. A case or controversy exists between AbbVie and Defendants regarding the infringement and validity of the '015 Patent.

250. Under the totality of the circumstances, there is a substantial controversy between AbbVie and Defendants having sufficient immediacy and reality to establish declaratory

judgment jurisdiction relating to Cipla's threatened infringement of the '015 Patent.

251. AbbVie will be substantially and irreparably damaged and harmed by the infringing activities described above unless those activities are enjoined by this Court. AbbVie does not have an adequate remedy at law.

252. In view of the foregoing, there exists a substantial controversy between AbbVie and Defendants, which have adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

SEVENTEENTH COUNT
DECLARATORY JUDGMENT AS TO THE '347 PATENT

253. Paragraphs 1–252 are incorporated herein by reference.

254. On information and belief, Defendants are actively seeking FDA approval to sell Cipla's Generic Lopinavir/Ritonavir Tablets for the same indication, the same dosages, and the same method of use as the Kaletra® products sold by AbbVie.

255. On information and belief, upon FDA approval of ANDA No. 090-371, Defendants will infringe one or more claims of the '347 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Cipla's Generic Lopinavir/Ritonavir Tablets, unless this Court orders that the effective date of any FDA approval of ANDA No. 090-371 shall be no earlier than the expiration date of the '347 Patent and any additional periods of exclusivity.

256. On information and belief, Defendants intend to commence sales of Cipla's Generic Lopinavir/Ritonavir Tablets immediately upon receiving final approval from the FDA.

257. On information and belief, in Cipla's ANDA No. 090-371, Cipla has represented to the FDA that Cipla's Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

258. On information and belief, therefore, Defendants' manufacture, importation, sale, and/or offer for sale of Cipla's Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would directly infringe one or more claims of the '347 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

259. Defendants have knowledge and are aware of AbbVie's '347 Patent, as evidenced by Cipla's Notice Letter.

260. A case or controversy exists between AbbVie and Defendants regarding the infringement and validity of the '347 Patent.

261. Under the totality of the circumstances, there is a substantial controversy between AbbVie and Defendants having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Defendants' threatened infringement of the '347 Patent.

262. AbbVie will be substantially and irreparably damaged and harmed by the infringing activities described above unless those activities are enjoined by this Court. AbbVie does not have an adequate remedy at law.

263. In view of the foregoing, there exists a substantial controversy between AbbVie and Defendants, which have adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

EIGHTEENTH COUNT
DECLARATORY JUDGMENT AS TO THE '878 PATENT

264. Paragraphs 1–263 are incorporated herein by reference.

265. On information and belief, Defendants are actively seeking FDA approval to sell Cipla's Generic Lopinavir/Ritonavir Tablets for the same indication, the same dosages, and the same method of use as the Kaletra® products sold by AbbVie.

266. On information and belief, upon FDA approval of ANDA No. 090-371,

Defendants will infringe one or more claims of the '878 Patent under 35 U.S.C. § 271(b), by actively inducing direct infringement by others (for example, by medical practitioners or patients), unless this Court orders that the effective date of any FDA approval of ANDA No. 090-371 shall be no earlier than the expiration date of the '878 Patent and any additional periods of exclusivity.

267. On information and belief, Defendants intend to commence sales of Cipla's Generic Lopinavir/Ritonavir Tablets immediately upon receiving final approval from the FDA.

268. On information and belief, in Cipla's ANDA No. 090-371, Cipla has represented to the FDA that Cipla's Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

269. On information and belief, Defendants' offering to sell, sale, making, and/or importation of Cipla's Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would actively induce infringement under 35 U.S.C. § 271(b) of at least one of the claims of the '878 Patent, either literally or under the doctrine of equivalents.

270. Defendants have knowledge and are aware of AbbVie's '878 Patent, as evidenced by Cipla's Notice Letter.

271. A case or controversy exists between AbbVie and Defendants regarding the infringement and validity of the '878 Patent.

272. Under the totality of the circumstances, there is a substantial controversy between AbbVie and Defendants having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Defendants' threatened infringement of the '878 Patent.

273. AbbVie will be substantially and irreparably damaged and harmed by the infringing activities described above unless those activities are enjoined by this Court. AbbVie

does not have an adequate remedy at law.

274. In view of the foregoing, there exists a substantial controversy between AbbVie and Defendants, which have adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

PRAYER FOR RELIEF

WHEREFORE, AbbVie respectfully requests that this Court enter judgment in its favor as follows:

a. declaring that, under 35 U.S.C. § 271(e)(2)(A), Defendants' submission of ANDA No. 090-371 to the FDA to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Cipla's Generic Lopinavir/Ritonavir Tablets before the expiration of the '359, '752, '899, '349, '613, '952, '015, '347, and '878 Patents was an act of infringement of each of the '359, '752, '899, '349, '613, '952, '015, '347, and '878 Patents;

b. declaring that Defendants' commercial manufacture, use, offer for sale, or sale in, or importation into the United States, of Cipla's Generic Lopinavir/Ritonavir Tablets would constitute direct infringement under 35 U.S.C. §§ 271(a) and/or 271(e)(2)(A) of one or more claims of each of the '359, '752, '899, '349, '015, and '347 Patents;

c. declaring that Defendants' commercial manufacture, use, offer for sale, or sale in, or importation into the United States, of Cipla's Generic Lopinavir/Ritonavir Tablets would constitute induced infringement of one or more claims of each of the '752, '613, '952, and '878 Patents;

d. declaring that Defendants would induce infringement of one or more claims of each of the '752, '613, '952, and '878 Patents under 35 U.S.C. §§ 271(b) and/or 271(e)(2)(A) by its manufacture, use, offer to sell, and sale in, and importation into the United States, of Cipla's

Generic Lopinavir/Ritonavir Tablets prior to expiration of the '752, '613, '952, and '878 Patents, and any additional dates of exclusivity;

e. enjoining Defendants, and all persons acting in concert with Defendants, from seeking, obtaining, or maintaining approval of ANDA No. 090-371 until the expiration of the '359, '752, '899, '349, '613, '952, '015, '347, and '878 Patents and any additional periods of exclusivity;

f. enjoining Defendants and all persons acting in concert with Defendants, from commercially manufacturing, using, offering for sale, or selling Cipla's Generic Lopinavir/Ritonavir Tablets within the United States, or importing into the United States Cipla's Generic Lopinavir/Ritonavir Tablets, until the expiration of the '359, '752, '899, '349, '613, '952, '015, '347, and '878 Patents, and any additional periods of exclusivity;

g. declaring the '359, '752, '899, '349, '613, '952, '015, '347, and '878 Patents valid and enforceable;

h. finding this to be an exceptional case and awarding AbbVie its costs, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. § 285;

i. awarding AbbVie its costs and expenses in this action; and

j. awarding AbbVie any further and additional relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ *Derek J. Fahnestock*

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November 10, 2017
11433971